UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MARIA MENDEZ, Plaintiff, v. RAHUL V. SHAH, M.D., *et al.*, Defendants.	:	Civil Action No. 13-1585 **OPINION**

Appearances:

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HILLMAN, District Judge:

Before the Court is a motion to dismiss the third amended complaint filed by defendants Medtronic Sofamaor Danesk USA Inc., Medtronic Spine LLC, Medtronic USA Inc., and Medtronic Inc. (collectively "Medtronic"). For the reasons stated below,

the motion will be granted.

I. BACKGROUND

The factual background was summarized in the Court's earlier Opinion, Mendez v. Shah, 28 F.Supp.3d 282 (D.N.J. 2014), and will not be repeated here.

Procedurally, the Court previously granted Medtronic's motion to dismiss plaintiff's second amended complaint in part. The Court dismissed Count V (implied warranty), Count VI (design defect), Count X (third party beneficiary), and Count XII (fraud). The Court also dismissed plaintiff's request for punitive damages as to any Medtronic device which had received premarket approval. The Court dismissed Count VII (express warranty), and Count VI (manufacturing defect and failure to warn), but without prejudice, and granted plaintiff leave to file an amended complaint to provide a more definite statement of her claims.

Plaintiff filed a third amended complaint which Medtronic now seeks to dismiss.

II. JURISDICTION

This Court exercises jurisdiction pursuant to 28 U.S.C. §

1332(a), diversity of citizenship. Plaintiff is a citizen of the Commonwealth of Pennsylvania and the defendants, are citizens of either the States of New Jersey, Tennessee, Delaware, or Minnesota. The amount in controversy exceeds the jurisdictional limit exclusive of interest and costs.

A Court exercising diversity jurisdiction must apply the law of the forum state within which it sits, and therefore, New Jersey law will apply to plaintiff's state law claims. See Chemical Leaman Tank Lines, Inc. V. Aetna Casualty and Surety Co., 89 F.3d 976, 983 (3d Cir. 1996) (stating that "[a]s a federal court sitting in diversity, we must apply the substantive law of New Jersey.") (citing Borse v. Piece Goods Shop, Inc., 963 F.2d 611, 613 (3d Cir. 1992)).

III. DISCUSSION

A. Standard for Motion to Dismiss

When considering a motion to dismiss a complaint for failure to state a claim upon which relief can be granted pursuant to Fed. R. Civ. P. 12(b)(6), a court must accept all well-pleaded allegations in the complaint as true and view them in the light most favorable to the plaintiff. Evancho v. Fisher, 423 F.3d 347, 351 (3d Cir. 2005). It is well settled that a pleading is sufficient if it contains "a short and plain

statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Under the liberal federal pleading rules, it is not necessary to plead evidence, and it is not necessary to plead all the facts that serve as a basis for the claim. Bogosian v. Gulf Oil Corp., 562 F.2d 434, 446 (3d Cir. 1977). However, "[a]lthough the Federal Rules of Civil Procedure do not require a claimant to set forth an intricately detailed description of the asserted basis for relief, they do require that the pleadings give defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests." Baldwin County Welcome Ctr. v. Brown, 466 U.S. 147, 149-50 n.3 (1984) (quotation and citation omitted).

A district court, in weighing a motion to dismiss, asks "'not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claim.'" Bell Atlantic v. Twombly, 127 S. Ct. 1955, 1969 n.8 (2007) (quoting Scheuer v. Rhoades, 416 U.S. 232, 236 (1974)); see also Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949 (2009) ("Our decision in Twombly expounded the pleading standard for 'all civil actions' . . . ."); Fowler v. UPMC Shadyside, 578 F.3d 203, 210 (3d Cir. 2009) ("Iqbal . . . provides the final nail-in-the-coffin for the 'no set of facts' standard that

applied to federal complaints before Twombly.").

Following the Twombly/Iqbal standard, the Third Circuit has outlined a three-part analysis in reviewing a complaint under Rule 12(b)(6). First, the Court must take note of the elements needed for plaintiff to state a claim. Santiago v. Warminster Tp., 629 F.3d 121, 130 (3d Cir. 2010). Second, the factual and legal elements of a claim should be separated; a district court must accept all of the complaint's well-pleaded facts as true, but may disregard any legal conclusions. Id.; Fowler, 578 F.3d at 210 (citing Iqbal, 129 S. Ct. at 1950). Third, a district court must then determine whether the facts alleged in the complaint are sufficient to show that the plaintiff has a plausible claim for relief. Id. A complaint must do more than allege the plaintiff's entitlement to relief. Fowler, 578 F.3d at 210; see also Phillips v. Cnty. of Allegheny, 515 F.3d 224, 234 (3d Cir. 2008) (stating that the "Supreme Court's Twombly formulation of the pleading standard can be summed up thus: 'stating . . . a claim requires a complaint with enough factual matter (taken as true) to suggest' the required element. This 'does not impose a probability requirement at the pleading stage,' but instead 'simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of'

the necessary element"). A court need not credit either "bald assertions" or "legal conclusions" in a complaint when deciding a motion to dismiss. In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1429-30 (3d Cir. 1997). The defendant bears the burden of showing that no claim has been presented. Hedges v. United States, 404 F.3d 744, 750 (3d Cir. 2005) (citing Kehr Packages, Inc. v. Fidelcor, Inc., 926 F.2d 1406, 1409 (3d Cir. 1991)).

Finally, a court in reviewing a Rule 12(b)(6) motion must only consider the facts alleged in the pleadings, the documents attached thereto as exhibits, and matters of judicial notice. Southern Cross Overseas Agencies, Inc. v. Kwong Shipping Group Ltd., 181 F.3d 410, 426 (3d Cir. 1999). A court may consider, however, "an undisputedly authentic document that a defendant attaches as an exhibit to a motion to dismiss if the plaintiff's claims are based on the document." Pension Benefit Guar. Corp. v. White Consol. Indus., Inc., 998 F.2d 1192, 1196 (3d Cir. 1993). If any other matters outside the pleadings are presented to the court, and the court does not exclude those matters, a Rule 12(b)(6) motion will be treated as a summary judgment motion pursuant to Rule 56. Fed. R. Civ. P. 12(b).

B. Analysis

A summary of the premarket approval process for the Infuse device, as well as the law regarding federal preemption, was provided in the Court's earlier Opinion and will not be repeated here. See Mendez, 28 F.Supp.3d at 289-93.

Plaintiff filed a third amended complaint bringing various claims of negligence and product liability against all defendants. This motion concerns only those counts directed at Medtronic, namely, Count IV (product liability under the New Jersey Product Liability Act), and Count V (breach of express warranty).

1. Product Liability

The New Jersey Product Liability Act ("PLA")[1] recognizes

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1 Under the New Jersey Product Liability Act (PLA),

> A manufacturer or seller of a product shall be liable in a product liability action only if the claimant proves by a preponderance of the evidence that the product causing the harm was not reasonably fit, suitable or safe for its intended purpose because it: a. deviated from the design specifications, formulae, or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae, or b. failed to contain adequate warnings or instructions, or c. was designed in a defective manner.

three claims: design defect, manufacturing defect, or failure to warn. See Roberts v. Rich Foods, Inc., 654 A.2d 1365 (N.J. 1995); Dziewiecki v. Bakula, 824 A.2d 241 (N.J. Super. Ct. App. Div. 2003). The standard of liability is that the product "was not reasonably fit, suitable or safe for its intended purpose." Cornett v. Johnson & Johnson, 998 A.2d 543 (N.J. Super. Ct. App. Div. 2010). To prove a defect, a plaintiff must be able to show that: (1) the product was defective; (2) the defect existed when product left the hands of the defendant; and (3) the defect caused the injury to a reasonably foreseeable user.'" McGarvey v. G.I. Joe Septic Service, Inc., 679 A.2d 733 (N.J. Super. Ct. App. Div. 1996)(citing Jurado v. Western Gear Works, 619 A.2d 1312 (N.J. 1993)). "To prove both the existence of a defect and that the defect existed while the product was in the control of the manufacturer, a plaintiff may resort to direct evidence, such as the testimony of an expert who has examined the product, or, in the absence of such evidence, to circumstantial proof." Myrlak v. Port Authority of New York and New Jersey, 723 A.2d 45, 52 (N.J. 1999) (citing Scanlon v. General Motors Corp., 326 A.2d 673 (N.J. 1974); Manieri v. Volkswagenwerk A.G., 376 A.2d

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N.J.S.A. 2A:58C-2.

1317 (N.J. Super. Ct. App. Div. 1977)). A plaintiff may also establish a defect by "negat[ing] other causes of the failure of the product for which the defendant would not be responsible, in order to make it reasonable to infer that a dangerous condition existed at the time the defendant had control [of the product]." Id. at 53 (citing Scanlon, 65 N.J. at 593-94).

Under New Jersey product liability law, "the injured plaintiff is not required to prove a specific manufacturer's defect." Id. at 52 (citing Moraca v. Ford Motor Co., 332 A.2d 599 (N.J. 1975)). "Proof that a product is not fit for its intended purposes 'requires only proof ... that 'something was wrong' with the product.'" Id. (citing Scanlon, 326 A.2d 673). However, the "mere occurrence of an accident and the mere fact that someone was injured are not sufficient to demonstrate the existence of a defect." Id.

In its earlier Opinion, the Court permitted plaintiff to amend her complaint and re-plead her manufacturing defect and failure to warn claim. Because plaintiff has not adequately identified the federal law that parallels her state law claims, her products liability claims will be dismissed.

As stated in the Court's previous Opinion, the Infuse

device is a Class III medical device that obtained PMA approval and is subject to the MDA express preemption provision. "[T]he MDA expressly pre-empts only state requirements different from, or in addition to, any requirement applicable ... to the device under federal law, § 360k(a)(1) ... ." Riegel v. Medtronic, Inc., 552 U.S. 312, 321, 128 S.Ct. 999 (2008) (internal quotation marks omitted). Thus, the MDA preemption clause does not apply to a state claim that parallels federal law. Id. at 330. Although plaintiff cannot simply state that her state law claim parallels federal law generally, how specific plaintiff needs to be varies among courts. Compare Wolicki-Gables v. Arrow Intern., Inc., 634 F.3d 1296, 1301 (11th Cir. 2011) with Bausch v. Stryker Corp., 630 F.3d 546, 555 (7th Cir. 2010).

Here, plaintiff states that "Medtronic failed to comply with the FDA's [] Good Manufacturing Practices with regard to InFuse and the Capstone Spinal System as to misbranding and adulteration,... ." Although citing to the FDA's Current Good Manufacturing Practices ("CGMP") could present a parallel federal claim,[2] plaintiff has not identified what regulations

[2] Medtronic argues that the CGMPs "generally do not constitute enforceable federal requirements capable of serving as a basis for a parallel claim[]" because they are too flexible and too generic. Although some courts have followed this idea, the

under the CGMPs regarding misbranding and adulteration parallel her state law claim. Pursuant to Riegel, it must be determined whether the plaintiff's common-law claims based upon New Jersey

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Seventh Circuit in Bausch provided sound reasoning for why the CGMPs are binding on manufacturers. Id. at 555. Specifically,

> Section 360k makes preemption a defense if a state seeks to impose on a manufacturer 'any requirement—(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.' 21 U.S.C. § 360k(a). We emphasize the phrase 'any requirement.' And federal law is clear: for manufacturers of Class III medical devices, the Quality System Regulations and Current Good Manufacturing Practices adopted by the FDA under its delegated regulatory authority are legally binding requirements 'under this chapter.' 21 C.F.R. § 820.1. 'The failure to comply with any applicable provision in this part [of the regulations] renders a device adulterated under section 501(h) of the act. Such a device, as well as any person responsible for the failure to comply, is subject to regulatory action.' 21 C.F.R. § 820.1(c).

The Court concluded that requiring concrete, product-specific requirements would leave injured patients without any remedy for a wide range of harmful violations of federal law. Id. ("The FDA regulations contain many requirements that are not concrete or product-specific, yet which are obviously vital to producing safe and effective medical devices."). This Court follows the reasoning of the Seventh Circuit and finds that the CGMPs are binding regulations imposed on manufacturers. See also, Howard v. Sulzer Orthopedics, Inc., 382 F. App'x 436, 440 (6th Cir. 2010) (finding plaintiff identified specific GMP that he thought had been violated, and rejecting defendant's argument that the relevant GMP is categorically unenforceable).

requirements with respect to the device are "different from, or in addition to," the federal ones, that relate to safety and effectiveness. Riegel, 552 U.S. at 321-22 (citing § 360k(a)). Without properly identifying the federal requirements, such a comparison cannot be made. Thus, plaintiff's product liability claims for manufacturing defect and failure to warn will be dismissed.[3]

2. Breach of Express Warranty

In its earlier Opinion, the Court permitted plaintiff to amend her complaint to provide more detail regarding her claim for breach of express warranty.[4] Because plaintiff has not

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3 Further, it appears that plaintiff has grounded her failure to warn claim on allegations that Medtronic failed to provide sufficient warnings on the outside of the Infuse Bone Graft product. Such a failure to warn claim would be preempted even if plaintiff had sufficiently alleged the federal requirement that parallels her state law claim. Medtronic has stated that the packaging and the warnings insert inside the package were approved by the FDA. Therefore, any argument that the warnings should have appeared on the outside of the Infuse Bone Graft product, a Class III device, is preempted because it would impose a requirement in addition to what the FDA approved. See Riegel, 552 U.S. at 321-22.

4 Medtronic does not argue that this claim is preempted and, indeed, most courts agree that an adequately pleaded claim for breach of express warranty is not expressly preempted. See, e.g., Byrnes v. Small, --- F.Supp.3d ----, No. 14-1726, 2015 WL 1243219, at *10 (M.D.Fla. Mar. 18, 2015); Wright v. Medtronic, Inc., --- F.Supp.3d ----, No. 13-716, 2015 WL 328596, at * 15 (W.D.Mich. Jan. 23, 2015); McPhee v. DePuy Orthopedics, Inc.,

pleaded sufficient facts that could suggest each element of her claim, her breach of express warranty claim will be dismissed.

"Under New Jersey law, in order to state a claim for breach of express warranty, Plaintiffs must properly allege: (1) that Defendant made an affirmation, promise or description about the product; (2) that this affirmation, promise or description became part of the basis of the bargain for the product; and (3) that the product ultimately did not conform to the affirmation, promise or description." Snyder v. Farnam Companies, Inc., 792 F.Supp.2d 712, 721 (D.N.J. 2011) (citing N.J. Stat. Ann. § 12A:2–313). "However, 'an affirmation merely of the value of the goods or a statement purporting to be merely the seller's opinion or commendation of the goods does not create a warranty.'" Id. (citing N.J. Stat. Ann. § 12A:2–313(2)). "Additionally, statements that are nothing more than mere puffery are not considered specific enough to create an express warranty." Id. (citations omitted). A plaintiff in a warranty action "need not establish the existence of a defect; the failure of the goods to perform as warranted is sufficient." Spring Motors Distributors, Inc. v. Ford Motor Co., 489 A.2d 660

989 F.Supp.2d 451, 465 (W.D.Pa. 2012).

(N.J. 1985). However, "[p]roof of causation must still be shown in a case based on breach of an express warranty". Ford Motor Credit Company, LLC v. Mendola, 48 A.3d 366, 375 (N.J. Super. Ct. App. Div. 2012) (citing Realmuto v. Straub Motors, Inc., 322 A.2d 440 (N.J. 1974)).

In her third amended complaint, plaintiff alleges that Medtronic "participated in an aggressive marketing campaign, including improper incentives, inducements, and kickbacks paid to physicians, hospitals, surgical centers and others, who would agree to push Medtronic's products for use in off-label and experimental spinal surgeries on patients, which included statements as to the safety of their products ... which dismissed or downplayed risks of such use, off-label use, or use in patients for whom the surgery would be unnecessary, contraindicated, experimental, or ill-advised." Plaintiff also alleges that "statements in Medtronic's literature, on-line and in television or other advertising," deliberately misrepresented the "results and outcomes of Medtronic studies and clinical trials and/or made by sales and marketing personnel, constituted express warranties."

Also, plaintiff alleges that employees of Medtronic

collaborated with physician authors who had significant financial relationships with the company to draft articles that downplayed or minimized the adverse events associated with InFuse when the product was used in various spinal fusion procedures. Plaintiff further alleges that these articles and their conclusions contained material misstatements of fact including the minimizing or omission of serious adverse events when InFuse (rhBMP-2) was used off-label and in unapproved ways.

Plaintiff states that her doctor relied upon the warranties and that Medtronic's agents were present in the hospitals and in the operating rooms for the purpose of illegally promoting off-label and experimental uses of the medical devices in unapproved procedures.

Plaintiff has not alleged sufficient facts that could suggest a claim for breach of express warranty. Plaintiff has not identified any examples of a false affirmation or promise made by Medtronic. Her reference to certain articles and studies which downplayed or minimized the adverse events associated with InFuse were made to the medical community at-large. Also, plaintiff has not identified any affirmations made to her by Medtronic or what affirmations she purportedly relied

upon. Further, plaintiff has not identified what statements in the articles she cites are allegedly false. Absent allegations that false statements made to plaintiff "became the basis of the bargain for the purchase of the good", no claim for breach of express warranty can be sustained. Liberty Lincoln-Mercury, Inc. v. Ford Motor Co., 171 F.3d 818, 825 (3d. Cir. 1999).

Therefore, plaintiff's breach of express warranty claim will be dismissed.

IV. CONCLUSION

For the foregoing reasons, Medtronic's motion to dismiss will be granted.

An appropriate order will be entered.

s/Noel L. Hillman
NOEL L. HILLMAN, U.S.D.J.

At Camden, New Jersey

Dated: March 30, 2015